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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 10/821,274   | 04/07/2004  | Michael W. Pantoliano | 044988-0308977      | 9875             |
| 21971  | 7590        | 09/22/2005            | EXAMINER            |                  |
| WILSON SONSINI GOODRICH & ROSATI<br>650 PAGE MILL ROAD<br>PALO ALTO, CA 94304-1050 |             |                       | ZHOU, SHUBO         |                  |
|  |             | ART UNIT              | PAPER NUMBER        |                  |
|  |             | 1631                  |                     |                  |
| DATE MAILED: 09/22/2005  |             |                       |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                              |                   |
|------------------------------|------------------------------|-------------------|
| <b>Office Action Summary</b> | Application No.              | Applicant(s)      |
|                              | 10/821,274                   | PANTOLIANO ET AL. |
|                              | Examiner<br>Shubo (Joe) Zhou | Art Unit<br>1631  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 July 2005.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 54-63 is/are pending in the application.
- 4a) Of the above claim(s) 60-63 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 54-59 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 54-63 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 07 April 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/7/04.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

JDD

**DETAILED ACTION**

***Election/Amendments***

1. Applicants' election, without traverse, of Group I (claims 54-59) in the communication filed 7/18/05 is acknowledged. Applicants' amendment to the claims is also acknowledged and entered.

Claims 54-63 are currently pending, claims 54-59 are under examination, and claims 60-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

***Preliminary Amendment***

2. The preliminary amendments to the specification, the claims and the drawings filed 4/7/04 are acknowledged. The amendment to the claims has been entered. The amendments to the specifications were not in compliance with 37 CFR 1.121(b), as set forth in the Office letter mailed 7/22/04. Applicants are hereby notified that the amendment to the drawings were also not in compliance with 37 CFR 1.121(d) because only marked-up copies of the amended drawings, but no "replacement sheets", were filed. Applicants are required to file the clean version of "replacement sheets" as in compliance with 37 CFR 1.121(d).

The preliminary amendments to the specification filed 8/10/04 as a response to the Office letter mailed 7/22/04, are acknowledged and entered.

***Information Disclosure Statement***

3. The Information Disclosure Statement filed 4/7/04 has been entered and considered. Initialed copies of the form PTO-1449 are enclosed with this action.

*Drawings*

4. As noted, *supra*, the preliminary amendments to the drawings filed 4/7/04 are not in compliance with 37 CFR 1.121(d).

*Specification*

5. The specification is objected to because of the following:

The title of the invention is not descriptive. The elected invention is drawn to a method for identifying a ligand that binds to a protein. The current title, however, is directed to “microplate thermal shift assay apparatus for ligand development and multi-variable protein chemistry optimization.” A new title is required that is clearly indicative of the invention to which the elected claims are directed.

It appears that trademarks are used in this application, such as ROBOCYCLER™ on page 1. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

***Claim Rejections-35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 54-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “the ligand” in claim 54, step (3) lacks clear antecedent basis and renders the claim indefinite. While the term “ligand” appears in the preamble of the claim, it is not in steps (1) and (2) preceding step (3). The terms “a molecule” and “the molecule” do appear in steps (1) and (2), respectively. It is not clear whether the term “the ligand” in step (3) meant “the molecule” in step (2).

Claims 55-59 are rejected due to their dependency from claim 54 hence also comprising the indefinite limitation.

Clarification of the metes and bounds of the claims is requested.

***Double Patenting Rejections***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 54-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 71-77 of US copending Application No. 09/801,676.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 54-59 of the instant application are drawn to a method for identifying a ligand that binds to a protein comprising the steps of (1) receiving unfolding data for a protein, (2) determining an unfolding temperature for the protein in the presence of test molecule, (3) comparing the unfolding temperature midpoint for the protein incubated with the test molecule with the unfolding temperature midpoint in the absence of any test molecules, and (4) determining that the test molecule binds to the protein when a difference between the unfolding temperature midpoint for the protein in the presence of the test molecule and the unfolding temperature midpoint in the absence of test molecules exceeds a threshold.

Claims 71-77 of US copending Application No. 09/801,676 are drawn to a method that comprises, *inter alia*, these same 4 steps. Claim 73 also recites fitting data with at least square algorithm based on an equation, which reads on claims 55-56 of the instant application. Claims 71-77 also recites estimating the ligand binding affinity, which reads on claims 57-58 of the instant application. Claim 74 requires “fluorescence unfolding data” (i.e.  $y(T)$  in the equation), which reads on claim 59 of the instant application.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this

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application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.



Patent Examiner

*Ardin H. Marschel 9/18/05*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**